EXHIBIT 22

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MASTER FILE NO. 2:12-MD-02327 MDL 2327
	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
LINDA J. MADDING; et al., Plaintiff,	
vs.	Case No. 2:12-CV-02512
ETHICON, INC., et al., Defendants.	

VIDEOTAPED DEPOSITION OF HUNTER A. MCKAY, M.D.

June 15, 2016

Seattle, Washington

surgical treatment of Mrs. Linda Madding?

A Yes.

Q And upon reviewing those records, did your memory become refreshed as to when you first treated Mrs. Madding?

A Yes. Thank you.

The first encounter was in 2003, and the exact date was November 10th, 2003.

Q I would like to direct your attention to Bates Page 64. It may be helpful here.

A How do I find 64?

Mine go up to 48-- no, 50-- I don't go beyond 52.

Q Let me see.

A Unless they're out of order.

Q I was referring to the Bates label on the bottom.

It begins at 59, and then it ends at 94.

A Oh, all right. Well, I didn't know what the Bates system was.

Q Okay. Is that clear now?

A Yes.

Q All right.

A Thank you.

Q So if you go to Bates Page 64--

A Yes.

Q Doctor, could you describe for the Ladies and Gentlemen of the Jury why it is that Mrs. Madding first sought your

treatment?

A Her symptoms were slow stream, difficulty emptying, intermittency, urinary frequency, and she also had evidence of urinary retention, and I believe urodynamic evidence of an obstructive voiding pattern.

Q And did she receive a set of diagnoses by you as a result of those symptoms?

A Yes. I felt that she had obstruction due to her TVT tape.

Q And what did you note underneath the urologic impression there at the time?

A Urinary retention, overactive bladder, and status post TVT.

Q Could you describe urinary retention for us?

A In the normal course of voiding, most folks empty all but 30 milliliters or less. That is their residual, is 30 milliliters or less. That is considered normal.

Anything greater than that is, to some degree, urinary retention.

It can be very mild, can be over a thousand milliliters.

Q What about Mrs. Madding allowed you to conclude that she was retaining urine?

A I think she had evidence of retention from Dr. Sleeter's office.

obstructive uropathy of the urethra due to mechanical obstruction.

Q So if I understand you correctly, you attempted to treat some of her symptomatology with medication, but not the urinary retention symptoms, correct?

A Well, antibiotics and anticholinergics may be helpful for some of these symptoms, but the main culprit here was obstruction, but we didn't know that for sure, and indeed she went three years after Dr. Sleeter's operation before she needed the takedown, so some patients only go three months and they need the takedown of the TVT.

Q There is something I would like to clear up here.

You said that she was experiencing retention she ultimately concluded was due to the TVT sling device, correct?

MR. JOHNSON: Object to form.

You can still answer.

THE WITNESS: Yes, so a little confusing to me as far as exactly what answer to offer you.

Could you repeat the question?

Q (By Mr. Kramer) I was just trying to summarize something that you also said.

A Oh.

Q I was asking-- you ultimately concluded she was

experiencing urinary retention due to the TVT sling device, correct?

MR. JOHNSON: Object to the form.

You can answer.

THE WITNESS: Let me rephrase your statement of what you thought I said.

MR. KRAMER: Sure. Go ahead.

THE WITNESS: The assumption, before going to the operating room, was that she had obstructive uropathy, and that she had a good chance of improving if we removed the obstructing TVT.

The proof of that was her clinical improvement after the procedure, so perhaps that answers the question.

The presumption is not a fulfilled hypothesis until the clinical results are in.

Q (By Mr. Kramer) That gives us a place to move forward.

To say that the TVT was causing obstruction was not to say that you thought the Ethicon TVT device was defective as of March 2005, right?

A I would agree with that statement.

Q And so that also means that in March of 2005 you would not have told Mrs. Madding that the Ethicon TVT device was defective, correct?

MR. JOHNSON: Object to the form.

THE WITNESS: I don't think I would

have said-- I would have used those words, no.

Q (By Mr. Kramer) Sitting here today, do you think that the Ethicon TVT device is a defective product?

A In the case that we are speaking about, Linda Madding, I do not believe the TVT is defective.

Q As we just discussed, you ultimately recommended a surgical takedown of the Ethicon TVT device for Mrs. Madding's symptoms, correct?

A Yes.

Q And so could you describe what a TVT takedown surgery would involve?

A Yes.

"Takedown" is a bit of a misnomer, but basically, if you can imagine a garden hose and then put a horseshoe underneath it, with the open end up, what we do is we take out that portion of the horseshoe that is beneath the garden hose, which is the portion of the tape which is beneath the urethra, and that is what we do.

We don't remove the entire tape for obstruction because there's usually no need to do that.

Q And so how much of the tape would you say you removed?

A Oh, maybe three centimeters, two to three centimeters typically.

Q And how-- strike that.

Do you know how much of the tape would be left

Q Does it appear to be an accurate reflection of a record that you yourself authored?
A Yes.
Q And is this the type of record that would be kept in the ordinary course of business at a medical practice?
A Yes.
Q Doctor, did you consider Mrs. Madding's March 2005 surgery a success?
A This report of April 6th, 2005 suggests that it was, since she was quite a bit improved.
Q And which of the symptoms specifically do you note that the March 2005 surgery helped resolve for Mrs. Linda Madding?
A Well, she had been getting up a couple of times at night having difficulty emptying, large residuals, frequency, and urgency, and my statement of April 6th says that all her symptoms improved, and her residual, instead of being 345, was now zero, so she was emptying better.
Q It seems like there was a pretty dramatic amount of improvement after your surgery of Mrs. Madding in March of 2005.

Is that correct?

A I think so.
Q Were there any symptoms at all that still remained that may have not been treated by the March 2005 TVT takedown

surgery?

A In Paragraph No. 2 I comment that her only symptom is occasional urge incontinence. That's an overactive bladder symptom, as we discussed earlier, but it has been occasional only, and so she was only wearing pads for security, not for repetitive need to change garments.

That's not uncommon after any sort of urologic procedure on the lower tract, that patients will have gradual improvement of their symptoms as things heal.

Q Doctor, to your knowledge, did Mrs. Madding have any complications related to her March 2005 surgery?

A Not that I'm aware of.

Q Doctor, when was the last time that you saw Mrs. Madding, to your memory?

A I think April 6th, 2005.

Q And--

A Correct me if I'm wrong.

Do you have records that state anything further beyond that?

Q I think the March 6th, 2005 record indicates, at the very bottom, that you told her to return on an as-needed basis, right?

MR. JOHNSON: You mean April 6th?

THE WITNESS: April 6th appears to be the last visit.

surgery?

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done TVT revisions?

A Six to ten.

Q What has been the reason for those revisions, if you can recall?

A Retention, erosion, bowel perforation requiring laparotomy.

Mostly erosion.

Q Can you just tell the jury what erosion is?

A If the vaginal epithelium does not heal over the tape, the tape is visible and palpable and present during intercourse and can be the source of chronic pain, drainage, frequency, urgency, urinary infections.

Q You saw Mrs. Madding on, I think, four different occasions or five different occasions.

At any time when you evaluated her, was there ever any evidence of erosion?

A No.

Q Was there ever any evidence of the vaginal epithelium not healing over the tension-free vaginal tape?

MR. KRAMER: Objection; form.

THE WITNESS: No.

Q (By Mr. Johnson) Was there ever any evidence that-- of exposure during the times that you evaluated Mrs. Madding?

A No.

Q In your evaluations of Mrs. Madding, they would have included pelvic examinations, correct?
A Yes.
Q Was one of the things that you were specifically looking for, evidence of any erosion or exposure of the transvaginal tape?
A Yes.
Q And at no time did you find any?
A I did not.
Q Now, I am going to turn to your care and treatment of Mrs. Madding.

I believe, during Counsel's questioning, we established that your first treatment was in November 2013, correct?

A Yes.
Q And your last treatment was in April of 2005?
A Yes.

(Exhibit No. 7 marked for identification.)

Q (By Mr. Johnson) I am going to hand you what we've marked as Exhibit No. 7.

Can you just identify this document for the jury?

A This is a consultation letter sent to the primary care doctor, Dr. Julie Komarow, dated November 10th, 2003, and

Q And my question-- because of time, I was trying to get to the end.

Did you have a final diagnosis at the end of your treatment of her, as to what her diagnosis had been?

MR. KRAMER: Objection; form.

THE WITNESS: Again, I am thinking out loud here when I say "working diagnosis," meaning, "I'm not sure exactly what's going on. Let's see if treatment is successful in a fashion that would cement the diagnosis of urethral syndrome."

Say the antibiotics work or cystoscopy with urethral dilatation improved the patient's symptoms, then we would say, "Well, this is not mechanical. This is something that is related to inflammation."

Q (By Mr. Johnson) So you prescribed some antibiotics?

A Yes, we decided to try that.

Q And did those work?

A No, not to my knowledge, because she obviously came back and still had some problems.

Q Was there any evidence, as of this time, November 10, 2003, that the mesh was infected?

A No.

Q Was there any evidence at any time, in your care and treatment of Mrs. Madding, that the mesh was infected?

A No.

A Yes.
Q During your surgery did you find any evidence of erosion or exposure of the mesh?
MR. KRAMER: Objection; form.
THE WITNESS: No.
Q (By Mr. Johnson) During your surgery did you find any evidence that the mesh was infected?
A No.
Q Did you find any evidence of any visible infection at the mesh site?
MR. KRAMER: Objection; form.
THE WITNESS: No.
Q (By Mr. Johnson) Did you find any evidence that the mesh had degraded in Ms. Madding's body?
MR. KRAMER: Form.
THE WITNESS: I don't know that I would be able to identify what degradation of mesh would look like, but to answer your question, I did not find any evidence of that.
Q (By Mr. Johnson) Did you find any evidence that the mesh that was being removed had curled in her body?
MR. KRAMER: Objection; form.
THE WITNESS: It's not mentioned in the operative report.
Q (By Mr. Johnson) Is that something you would typically

mention, if you had noted curling of the mesh?

MR. KRAMER: Objection; form.

THE WITNESS: I believe I would.

Q (By Mr. Johnson) Did you-- is there any-- was there any evidence, at the time of surgery, that the mesh had roped?

MR. KRAMER: Objection; form.

THE WITNESS: I don't know what "roped" means.

Q (By Mr. Johnson) I think it kind of spins on itself like a rope.

A No, I did not.

Q Is that something that you would have noted if you had seen it?

MR. KRAMER: Objection; form.

THE WITNESS: Probably.

Q (By Mr. Johnson) Was there any evidence, Dr. McKay, of any fraying of the mesh?

MR. KRAMER: Objection; form.

THE WITNESS: It's not mentioned, so I have no independent recollection.

Q (By Mr. Johnson) Is that something that you would typically mention if you saw that?

MR. KRAMER: Objection; form.

THE WITNESS: Perhaps.

Q (By Mr. Johnson) During your surgery and removal of the mesh, did you see any abnormality of the mesh?

MR. KRAMER: Objection; form.

THE WITNESS: I only have my operative report to go by, and there's no mention of it, so--

Q (By Mr. Johnson) Would it be your typical custom and practice, if you did see an abnormality in the mesh, to make a note of that in your operative report?

MR. KRAMER: Objection; form.

THE WITNESS: Probably.

(Exhibit No. 14 marked for identification.)

Q (By Mr. Johnson) And then just handing you what we marked as Exhibit No. 14, does this appear to be a true and correct copy of the anesthesia record for your surgery of March 1st?

A Yes.

Q And does that indicate the time the surgery started?

A Yes.

Q And what time was that?

A 0900.

Q And when was the surgery finished?

A 0953.

Q So the surgical time for you as a surgeon was 53 minutes

(Exhibit No. 19 marked for identification.)

VIDEOGRAPHER: We are back on the record. The time is 1:25 p.m.

Q (By Mr. Johnson) Doctor, I am handing you what we've marked as Exhibit No. 19, which I believe are notes that you brought with you to the deposition today.

Are these notes that you made in preparation for the deposition so you could know landmark dates and times?

A Yes.

Q And does it also indicate some of the time that you spent on the case?

A Yes.

Q Okay. Now I am going to change the subject back to your informed consent that you gave to Mrs. Madding before actually performing the surgery.

That's an informed consent you would have given on February 14th, 2005; is that right?

A Yes.

Q Did you indicate to Mrs. Madding, at that time, what the alternatives were for her, if any?

A Well, we had exhausted the conservative options, and of course there's always the option of no surgery.

I never insist that a patient undergo a surgical

procedure.

Q At that point in time had you concluded, based upon your review of Dr. Sleeter's records, your own evaluation, care, and treatment of Ms. Madding, that it was likely that there was an obstruction of the urethra that was causing the retention, and that that obstruction was due to the presence of the mesh?

A Yes.

Q Did you tell her that?

MR. KRAMER: Objection; form.

THE WITNESS: I don't have an independent recollection, so I don't know what I told her. I can only refer to the notes.

Q (By Mr. Johnson) Based upon your normal custom and practice, is that something that you would typically discuss with a patient before doing a surgery?

MR. KRAMER: Objection; form.

THE WITNESS: I am not sure what the word "that" refers to.

Q (By Mr. Johnson) Well, okay, let me ask a specific question--

A Rephrase, please.

Q In the context of a patient similar to Ms. Madding, who has a TVT placed, has several years of retention, and continues with those retention symptoms, you've tried

conservative attempts with medication, you tried conservative attempts with dilation, and you've concluded that it's probably some kind of mechanical obstruction of the urethra that's causing the retention, based on your custom and practice would you tell the patient that that's what you think is probably going on?

MR. KRAMER: Objection; form.

THE WITNESS: I think we would have a frank discussion about the likely diagnosis, which is obstruction, and the likely culprit being the previous TVT.

Q (By Mr. Johnson) I think you indicated-- during your prior testimony, when you were asked by Counsel, you indicated that in this particular case you don't believe that this obstruction occurred because the TVT was defective; is that correct?

A I would say there was no apparent defect of the material.

Q And I just have-- I wrote down in my notes that-- I have a quote, "In the case we are talking about, I do not believe it was defective," end quote.

When you were referring to it, are you just indicating that you are not aware of any defect in the product that caused her retention?

A Yes.

MR. JOHNSON: That's all I have.

EXHIBIT 23

ASSOCIATED UROLOGISTS
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February 14, 2005

FEB 18 2005

Julie Komarow, M.D.
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RE: LINDA J. MADDING

Dear Julie:

Mrs. Madding is on the schedule for a "take down" of her TVT on March 1. Hopefully we can afford her some measure of relief, especially given her large residual urines, including today's value of 348 mL. I discussed with her the very slight risk of worsening continence and the remote risk of urethral vaginal fistula. I will keep you posted as events unfold.

Best personal regards,

Hunter A. McKay, M.D., F.A.C.S.

HAM/sts

cc: Tamara Sleeter, M.D.